

**REMARKS**

The Official Action of October 28, 2009 constitutes a non-final rejection of the claims. The Official Action and the references relied upon therein have been carefully reviewed. Reconsideration and allowance of the claims are requested in view of the foregoing amendments and the following remarks.

**I. Claim Status and Amendments**

Claims 24-46 were pending in this application when last examined. Claim 28 has been withdrawn as non-elected subject matter.

Claims 24-27 and 29-46 have been examined on the merits and stand rejected. Claims 24-27 and 29-46 have also been objected to. No claims have been allowed.

The specification has been amended to reference the priority information at page 1, immediately after the title.

The specification has also been amended to remove reference to a hyperlink at page 21.

By way of the present amendment, the claims have been amended in a non-narrowing manner to address formal matters raised by the Examiner and to make minor editorial revisions to better conform to U.S. claim form and practice. Such revisions are unrelated to patentability. The revisions are non-substantive and not intended to narrow the scope of protection. Support can be found in the original claims as filed. The

revisions include: replacing the "characterized by" language with "wherein"; revising the beginning of the claims to recite "A" or "The"; and revising the claim language to provide proper antecedent basis throughout the claims. In keeping with US law, the use of "a" or "an" in patent parlance carries the meaning of "one or more".

Claims 24 and 25 have been amended to incorporate claims 26, 27 and 29, which are now cancelled without prejudice or disclaimer thereto. Claim 30 is amended to depend on claim 24.

No new matter has been added by the above amendments.

Claims 24, 25, 28 and 30-46 are pending upon entry of this amendment, and these claims define patentable subject matter warranting their allowance for the reasons discussed herein.

## **II. Priority Claim**

Applicants note with appreciation the Examiner's acknowledgement of the priority claim and the receipt of the foreign priority papers filed under § 119.

Pursuant to the Examiner's request on page 3 of the Official Action, the specification has been amended to reference the priority information at page 1, immediately after the title.

**III. Objection to the Specification**

On page 3 of the Official Action, the Examiner objects to the specification for improperly reciting a hyperlink at the top of page 21.

The present amendment renders the objection moot by amending the disclosure to remove reference to the hyperlink at page 21. Withdrawal of the objection is in order.

**IV. Claim Objections**

Claims 24-27 and 29-46 have been objected to for minor informalities for the reasons on page 3 of the Action. The Examiner contends that the claims appear to be a word for word translation of Japanese into English and are very difficult to understand.

As noted above, the present amendment overcomes the objection by amending the claims, in a non-narrowing manner, to make minor editorial revisions to better conform to U.S. claim form and practice. Withdrawal of the objection is requested.

The present amendment hereby cancels claim 27, thereby rendering the objection to claim 27 moot. Withdrawal of the objection is requested.

**V. Indefiniteness Rejections - 35 U.S.C. § 112**

Claims 24-26 and 45 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons on

pages 4-5 of the Official Action. This rejection is respectfully traversed.

To start, it is again noted that the claims have been amended to better define the claimed subject matter more clearly and distinctively in a non-narrowing manner to overcome this rejection for reasons which are self-evident. It should be noted that the objected language has been removed.

Claim 40 is amended to remove the extra "and" in the Markush listing.

Claim 46 has been amended to specify a protein "produced by" to overcome the Examiner's rejection.

As set forth in MPEP § 2173.02 (Eighth Ed., Rev. 7 (July 2008)), definiteness of claim language is analyzed, not in a vacuum, but in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.

As to the term "production amount potentiating factor" and "potentiating" in claims 24 and 26, the specification, at paragraph [0043] of the corresponding published patent application no. 20090099338, explains these terms when it states:

In order to accomplish the aforementioned objects, the present inventors intensively continued to study and, as a result, found out that, by expressing a gene encoding a factor having the action of increasing protein biosynthesis activity and/or anti-

apoptosis activity, inter alia, a gene encoding a factor having the action of inhibiting caspase activity, desirably, a baculovirus P35 gene in a recombinant animal cell producing a protein using fibrinogen, ecarin and factor VIII which were difficult to be mass-produced by the previous technique as one example of a protein to be produced, the effect of potentiating the protein producing ability which has not previously been seen, which resulted in completion of the present invention. Further, the present inventors have revealed that this potentiation of the production amount has two cases of the case where this factor contributes to potentiation of protein biosynthesizing activity as a factor for potentiating the production amount, and the case where the factor contributes to apoptosis activity inhibition and, in the former case, since the potentiation of the production amount is obtained before term of apoptosis occurrence, it was found to be very high in industrial utilization value without selecting a medium. [Emphasis added.]

At paragraph [0045], it is further discloses that the present invention relates to a recombinant protein producing cell which highly expresses the protein.

At paragraph [0055], it is described that:

The method of the present invention is characterized by a method using a recombinant animal cell highly producing a protein, the method comprising a step of expressing a gene encoding a factor having the action of allowing a host animal cell producing a protein to increase protein biosynthesis activity and/or anti-apoptosis activity, inter alia, a gene encoding a factor having the action of directly inhibiting caspase activity, for example, a

baculovirus P35 gene in a recombinant animal cell producing a protein. [Emphasis added.]

Based on this explanation and similar descriptions found throughout the disclosure, it should be clear that the terms "production amount potentiating factor" and "potentiating factor" mean factors that enhance the amount of protein produced/expressed by the transformed cell. This can be done by enhancing protein biosynthesis activity, i.e., increasing the synthesis of the protein, or by a factor which inhibits apoptosis activity so that. In the former case, the potentiation of the production amount is obtained before term of apoptosis occurrence. See also the explanation, for example, at paragraphs [0004] to [0005] in the disclosure regarding the term "caspase activity" and its relationship and effect on apoptosis, such as the description of a factor which acts downstream of the caspase cascade (inhibits the directly activity of the caspase) to exhibit the cell death suppressing effect." Accordingly, a factor having caspase activity inhibiting activity acts to inhibit the effects of apoptosis. All of this in turn results in increased expression levels and/or decreases on the effect of apoptosis.

Accordingly, it is believed that the skilled artisan, upon reading the disclosure, would clearly understand the metes and bounds of the objected claim language.

In addition, the claims have been amended to further define certain of these terms by incorporating subject matter from dependent claims. Thus, it is believed that the noted language is clear and definite.

The claims are thus clear, definite and have full antecedent basis. This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

**VI. Prior Art Rejections**

Claims 24-27, 35, 41, and 46 have been rejected under 35 U.S.C. § 102(b) as anticipated by Lin et al. (In Vitro Cell. Dev. Biol.-Animal, 37, 293-302, 2001) for the reasons on page 5 of the Action.

Claims 29-34, 36-40, and 42-45 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin et al. in view of Hui (US 6,187,588) for the reasons on pages 6-7.

These rejections are respectfully traversed and will be discussed together below as Lin et al. is the primary reference used in each rejection.

For the sole purpose of expediting prosecution, the present amendment obviates the anticipation rejection by amending the main claims to incorporate subject matter of claims not included in the rejection. Thus, the anticipation is rendered moot.

As to the obviousness rejection, it is respectfully submitted this rejection should fall, because the references fail to disclose or suggest each feature of the combined elements of the amended claims, as required for obviousness. Moreover, it is respectfully submitted that it would be impossible for one of ordinary skill to combine Lin et al and Hui et al. for the following reasons. The purpose of Hui et al is to increase the efficiency of transfection of cells with materials which depress a factor having caspase activity. However, Hui et al. is not concerned with expression of a protein. Indeed, Hui et al. does not show any expression of desired extraneous gene.

By contrast, the present invention relates to a method for preparing a highly produced protein by using a recombinant animal cell, as claimed. Again, the teachings in Hui et al. relates to transfection, not protein expression. Accordingly, it should be clear that the subject of the present invention is different from that of Hui et al.

Given these differences, it is important to note that the Examiner fails to show why one of ordinary skill would want to substitute the Sf9 cell of Lin, with the CHO cell of Hui et al., which reference again relates to transfection, not expression. Further, Hui et al. does not show a concrete use of CHO cells. Based on the above, it is respectfully submitted that the skilled artisan would not have been motivated to combine



and/or alter the teachings of Lin and Hui to arrive at the claimed invention. Thus, it is believed that independent claims 24 and 25, and all claims dependent thereon, are patentable over the combination of Lin and Hui. Therefore, the obviousness rejection is untenable and should be withdrawn.

**VII. Conclusion**

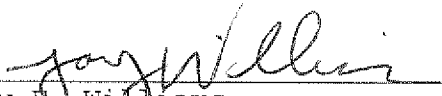
Having addressed all the outstanding issues, this paper is believed to be fully responsive to the Office Action. It is respectfully submitted that the claims are in condition for allowance and favorable action thereon is requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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